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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/799,059 | 03/12/2004 | Kenneth A. Alley | ALLE-P12-US | 6741 |
| 21616 | 7590 | 10/24/2005 | EXAMINER | |
| LAW OFFICES OF MARK A. GARZIA, P.C. 2058 CHICHESTER AVE BOOTHWYN, PA 19061 | | | PATEL, MITAL B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |
| DATE MAILED: 10/24/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,059

Applicant(s)

ALLEY, KENNETH A.

Examiner

Mital B. Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/6/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claim 4 is withdrawn in view of the newly discovered reference(s) to Koskela et al (WO 00/64520). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Koskela et al (WO 00/64520).

4. **As to claim 1**, Koskela et al teaches an inhaler for delivering drugs/medications by inhalation, the inhaler device comprising of: a) a housing (**See Fig. 2**) defining an inlet, an outlet spaced from said inlet, and an airflow path from said inlet to said outlet, said outlet comprises a mouthpiece **11**; b) a plurality of storage chambers **1,2** for storing a plurality of medications; c) means **6** that communicate with said drug storage chambers for withdrawing a pre-determined amount of medication from one or more chambers; and d) means **5,13** to simultaneously dispense said withdrawn medication during a single inhalation activity/event, and said mouthpiece includes a plurality of drug

passageways **20,21** for isolating each individual medication as the user of the device evacuates the prescribed dose.

5. **As to claim 2**, Koskela et al teaches an inhaler wherein said outlet comprises a mouthpiece **11**.

6. **As to claim 3**, Koskela et al teaches an inhaler wherein said mouthpiece isolates each individual drug passageway during each inhalation activity/event (**See page 5**).

7. **As to claim 5**, Koskela et al teaches an inhaler wherein said inhaler comprises a plurality of dosing discs **7a, 7b**.

8. **As to claim 6**, Koskela et al teaches an inhaler where said inhaler further comprises a plurality of channels (**See Fig. 4d**) for isolate said medications until they exit the outlet during the evacuation process.

9. **As to claim 7**, Koskela et al teaches an inhaler where said inhaler includes a combination of a dry powder drug with a pressurized chamber to help evacuate the drug or to include an additional aerosol medication simultaneously with the dry powder.

10. **As to claim 8**, Koskela et al teaches an inhaler for delivering drugs/medications by inhalation, the inhaler device comprising of: a) a housing (**See Fig. 2**) defining an inlet, an outlet spaced from said inlet, and an airflow path from said inlet to said outlet; b) a plurality of storage chambers **1,2** for storing a plurality of medications; c) a rotatable dosing disc **6** having a plurality of dosing wells **7a,7b** that communicate with said drug storage chambers for withdrawing a pre-determined amount of medication from one or more chambers; and d) air passageway platform **12** having a plurality of passageway channels **20,21**, said air passageway channels communicating with both the dosing

Art Unit: 3743

wells and said outlet of the mouthpiece **11** to define multiple air passageways for delivering said withdrawn medication during a single inhalation activity/event.

11. **As to claim 9**, Koskela et al teaches an inhaler wherein said multiple air passageways allow biaxial airflow to move the medicaments through the inhaler and out the outlet.

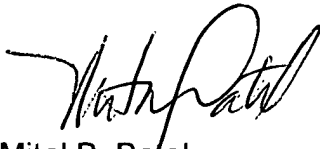
12. **As to claim 10**, Koskela et al teaches an inhaler further comprising pressurized cartridges **17** that communicate with the dosing wells for ensuring the complete evacuation of the medicaments from the wells, the air passageways and the outlet during the inhalation event.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 7/24/05
Mital B. Patel
Examiner
Art Unit 3743